## **Complete Summary**

#### **GUIDELINE TITLE**

Adalimumab for the treatment of psoriatic arthritis.

#### **BIBLIOGRAPHIC SOURCE(S)**

National Institute for Health and Clinical Excellence (NICE). Adalimumab for the treatment of psoriatic arthritis. London (UK): National Institute for Health and Clinical Excellence (NICE); 2007 Aug. 26 p. (Technology appraisal guidance; no. 125).

#### **GUIDELINE STATUS**

This is the current release of the guideline.

#### **COMPLETE SUMMARY CONTENT**

**SCOPE** 

METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS QUALIFYING STATEMENTS

IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY DISCLAIMER

#### SCOPE

## **DISEASE/CONDITION(S)**

Psoriatic arthritis (active and progressive)

#### **GUIDELINE CATEGORY**

Assessment of Therapeutic Effectiveness Treatment

#### **CLINICAL SPECIALTY**

Dermatology Family Practice Internal Medicine Radiology Rheumatology

#### **INTENDED USERS**

Advanced Practice Nurses Nurses Physician Assistants Physicians

## **GUIDELINE OBJECTIVE(S)**

To evaluate the clinical effectiveness and cost-effectiveness of adalimumab for the treatment of moderate to severe psoriatic arthritis in adults

#### **TARGET POPULATION**

Adult patients with psoriatic arthritis

#### INTERVENTIONS AND PRACTICES CONSIDERED

Adalimumab as an optional treatment

#### **MAJOR OUTCOMES CONSIDERED**

- Clinical effectiveness
  - Arthritic manifestations of psoriatic arthritis
  - Joint destruction
  - Physician's global assessment (PGA)
  - Disability
  - Quality of life
  - Frequency of adverse effects
- Cost-effectiveness

#### METHODOLOGY

## METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Hand-searches of Published Literature (Secondary Sources) Searches of Electronic Databases

#### **DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE**

**Note from the National Guideline Clearinghouse (NGC)**: The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an Evidence Review Group (ERG) report. The ERG report for this technology appraisal was prepared by the Centre for

Health Economics, University of York and Regional Drug and Therapeutics Centre (Newcastle) (see the "Availability of Companion Documents" field).

#### **Clinical Effectiveness**

### **Search Strategy**

A systematic literature search was undertaken by the ERG to verify the completeness of the methodology used by the manufacturer to retrieve relevant clinical studies presented in the submission.

Searches were undertaken on the following resources to identify relevant clinical effectiveness data: MedLine, Embase, Science Citation Index, Cochrane Library, the European League Against Rheumatism (EULAR), American College of Rheumatology (ACR), British Society for Rheumatology (BSR), Food and Drug Administration (FDA), European Medicines Agency (EMEA), and National Institute for Health and Clinical Excellence (NICE). All databases were searched from their inception to the date of the search. No language or other restrictions were applied to the study selection. The bibliographies of all included studies and the manufacturer's submission were reviewed to identify any further relevant studies. Due to the paucity of efficacy data available trials reported as abstracts were included in the review.

#### Inclusion criteria:

**Participants**: Adults with psoriatic arthritis (PsA)

**Interventions**: Adalimumab administered by subcutaneous injection for the treatment of PsA.

**Comparator**: Placebo or any other active agent.

**Outcomes**: No restrictions applied; (outcomes included: American College of Rheumatology [ACR] response criteria, total sharp score [TSS], psoriatic arthritis response criteria [PsARC], psoriasis area and severity index [PASI], health assessment questionnaire [HAQ], SF-36 and functional assessment of chronic illness therapy [FACIT])

**Design**: Randomised controlled trials (RCTs) and open-label extension studies were included in the evaluation of efficacy.

#### Exclusion criteria:

**Participants**: Juveniles with PsA (<16 years of age)

**Intervention**: Adalimumab for other indications (e.g. rheumatoid arthritis and ankylosing spondylitis)

**Study selection**: Peer review panel

Refer to Appendix 1in the ERG Report (see the "Availability of Companion Documents" field) for additional information on the search strategy.

#### **Cost-Effectiveness**

#### **Existing Cost-Effectiveness Evidence**

As part of the manufacturer's submission, a systematic search was undertaken with the aim of identifying published studies evaluating the cost-effectiveness of adalimumab for the treatment of moderate to severe psoriatic arthritis. The search strategy, key words, date range and sources searched to identify the economic studies were appropriate for this purpose. The manufacturer's search did not identify any studies which evaluated the cost-effectiveness of adalimumab for this indication. Two published studies assessing the cost-effectiveness of alternative anti-tumor necrosis factor (TNF) agents were identified and subjected to a detailed critical appraisal by the manufacturer.

The searches undertaken by the manufacturer were replicated by the ERG in order to validate the evidence base considered. The ERG found that the search was reproducible, and the results were consistent with the original search. However, it was not clear from the company submission how many different results met their search criteria, as they did not show how many of them were duplicated among the databases.

A second search was conducted by the ERG using a much broader search strategy designed to capture all National Health Service Economic Evaluation Database (NHS EED) records relating to PsA. In addition, the ERG ran searches of the NHS EED administrative system (CAIRS B) and of Medline, Cinahl, Embase and EconLit to identify any recent studies not yet screened for NHS EED. After deduplication there were 16 potential studies that met the inclusion criteria. Of the 16 studies identified, only 2 of these were full cost-effectiveness analyses. Both studies assessed the cost-effectiveness of alternative anti-TNF agents (etanercept and infliximab). Refer to Appendix 5 in the ERG Report (see the "Availability of Companion Documents" field) for details of the search strategies conducted by the ERG.

#### **NUMBER OF SOURCE DOCUMENTS**

#### **Clinical Effectiveness**

- The manufacturer identified 4 studies.
- Other than several abstracts derived from the two studies included in the manufacturer's submission no other relevant clinical studies were found during the literature search. Data from these abstracts were included only if they provided additional evidence with respect to the decision problem.

#### **Cost-Effectiveness**

• The Evidence Review Group (ERG) concurs with the manufacturer that there are no existing published cost-effectiveness studies evaluating the use of adalimumab for the treatment of moderate to severe psoriatic arthritis.

• Two published studies assessing the cost-effectiveness of alternative anti-TNF agents were identified by the manufacturer.

## METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

**Expert Consensus** 

#### RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

#### METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis Review of Published Meta-Analyses Systematic Review with Evidence Tables

#### **DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE**

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an Evidence Review Group (ERG) report. The ERG report for this technology appraisal was prepared by the Centre for Health Economics, University of York and Regional Drug and Therapeutics Centre (Newcastle) (see the "Availability of Companion Documents" field).

#### **Clinical Effectiveness**

#### **Submission Trial Analysis**

All studies included in the clinical evidence section of the Abbott submission were subjected to a detailed critical appraisal (refer to Appendix 2 in the ERG Report [see the "Availability of Companion Documents" field]). Studies were appraised by one reviewer and independently checked by a second reviewer. Disagreements were resolved through consensus, consulting a third reviewer if necessary. The resultant appraisals were then compared to the data presented in the submission. Data from studies presented in multiple abstracts were extracted and reported as a single study with all other relevant publications listed.

## **Meta-Analysis**

In the submission Abbott presented a meta-analysis of 2 studies. The meta-analysis was conducted using RevMan 4.2.9. Heterogeneity was investigated for all outcome measures using the Chi-squared test and showed no significant statistical heterogeneity (p<0.0001 for all outcomes), suggesting it was appropriate to use a fixed effects model. A fixed effects analysis assumes that only within-study variation is taken to influence the uncertainty of results. However, there were some notable differences between the two study populations with regards to disease-modifying anti-rheumatic drug (DMARD) use. The

robustness of the results was, therefore, also examined using the more 'conservative' random effects model which includes both within-study and between-study variation in the assessment of uncertainty. Overall the results provided by these different modelling assumptions were very similar, with only marginally wider confidence intervals using the random effects model.

Refer to Section 3.3 and Appendix 2 in the ERG report (see the "Availability of Companion Documents" field) for more information.

#### **Economic Evaluation**

The manufacturer's submission is based on a *de-novo* economic evaluation to estimate the cost-effectiveness of adalimumab for the treatment of moderate to severe psoriatic arthritis (PsA).

#### **Model Structure**

The model uses a form of micro-simulation known as an individual sampling model to describe the natural history of psoriatic arthritis disease, modelling individual patient histories from time of entry into the model until death (i.e. lifetime horizon). The model uses Monte-Carlo simulation at the patient level. At each decision node a random number decides the route a patient takes based on calculated probability, so each hypothetical patient represents only one possible route that can be taken.

Patients with active disease having failed two previous DMARD therapies enter the model. They start on their first treatment (adalimumab, etanercept, infliximab or conventional DMARDs) and remain on it for 6-month cycles until they no longer respond, at which point they then switch onto the next drug in the treatment sequence. Alternative treatment sequences for the anti-TNF agents are not considered such that all patients are assumed to receive conventional DMARDs after failure of initial therapy. For the base-case analysis, initial response (and hence the decision to continue with the first treatment) is defined as meeting the 12-week PsARC response criteria, which is sampled from the joint distribution of their American College of Rheumatology (ACR), psoriatic arthritis response criteria (PsARC) and psoriasis area and severity index (PASI) responses. Based on the type of response and the baseline characteristics for each simulated patient, their improvement in health assessment questionnaire (HAQ) and PASI is then predicted.

### **Critique of the Manufacturer's Economic Evaluation**

The ERG has considered the methods applied in the manufacturer's economic evaluation in the context of the critical appraisal questions listed in Table 5.12 of the ERG Report (see the "Availability of Companion Documents" field) which are drawn from common checklists for economic evaluation methods.

#### Evidence Synthesis Methods

In general the ERG found that the methods employed by the manufacturer lacked transparency which made it difficult to assess the validity of the findings. The ERG

felt that the general approach was overly complex employing a number of assumptions which increase the possibility of significant bias in the subsequent results. The key issues identified by the ERG include:

- The inclusion/exclusion criteria applied by the manufacturer in selecting studies for the indirect synthesis
- The assumption of exchangeability of response rates after adjustment for the number of patients with psoriasis at baseline
- The approach used to estimate correlation between response parameters
- The adjustment used by the manufacturer to estimate 12-week response parameters from 24-week trial results

Refer to Section 5 of the ERG Report (see the "Availability of Companion Documents" field) for more information.

#### METHODS USED TO FORMULATE THE RECOMMENDATIONS

**Expert Consensus** 

## DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

#### Considerations

Technology appraisal recommendations are based on a review of clinical and economic evidence.

#### **Technology Appraisal Process**

The National Institute for Health and Clinical Excellence (NICE) invites 'consultee' and 'commentator' organisations to take part in the appraisal process. Consultee organisations include national groups representing patients and carers, the bodies representing health professionals, and the manufacturers of the technology under review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents.

Commentator organisations include manufacturers of the products with which the technology is being compared, the National Health Service (NHS) Quality Improvement Scotland and research groups working in the area. They can comment on the evidence and other documents but are not asked to submit evidence themselves.

NICE then commissions an independent academic centre to review published evidence on the technology and prepare an 'assessment report'. Consultees and commentators are invited to comment on the report. The assessment report and the comments on it are then drawn together in a document called the evaluation report.

An independent Appraisal Committee then considers the evaluation report. It holds a meeting where it hears direct, spoken evidence from nominated clinical experts, patients and carers. The Committee uses all the evidence to make its

first recommendations, in a document called the 'appraisal consultation document' (ACD). NICE sends all the consultees and commentators a copy of this document and posts it on the NICE website. Further comments are invited from everyone taking part.

When the Committee meets again it considers any comments submitted on the ACD; then it prepares its final recommendations in a document called the 'final appraisal determination' (FAD). This is submitted to NICE for approval.

Consultees have a chance to appeal against the final recommendations in the FAD. If there are no appeals, the final recommendations become the basis of the guidance that NICE issues.

## Who is on the Appraisal Committee?

NICE technology appraisal recommendations are prepared by an independent committee. This includes health professionals working in the NHS and people who are familiar with the issues affecting patients and carers. Although the Appraisal Committee seeks the views of organisations representing health professionals, patients, carers, manufacturers and government, its advice is independent of any vested interests.

#### RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

#### COST ANALYSIS

The manufacturer submitted a cost–utility model assessing the impact of treatment with adalimumab compared with other anti-tumour necrosis factor (TNF)-alpha agents (etanercept or infliximab) or disease-modifying anti-rheumatic drugs (DMARDs) on both arthritis and skin outcomes. The model used a Monte-Carlo simulation at the patient level. In the model, treatment only continued if there was a response (defined as meeting psoriatic arthritis response criteria [PsARC] response criteria) at 12 weeks. It was assumed that people received conventional DMARD therapy after their psoriatic arthritis (PsA) failed to respond to treatment. Regression analysis was used to predict the health assessment questionnaire (HAQ) and psoriasis area and severity index (PASI) scores of the individual modelled patients based on American College of Rheumatology (ACR) and PASI response data. The predicted HAQ and PASI scores were then used to estimate both costs and utilities. Cycle length was 6 months, and a lifetime horizon was presented.

The base-case analysis compared adalimumab with etanercept, infliximab or DMARD. In the original manufacturer's submission, the incremental cost-effectiveness ratio (ICER) for adalimumab compared with DMARD was 25,991 pounds sterling per quality-adjusted life year (QALY) gained, etanercept was dominated by adalimumab (that is, etanercept was less effective and more costly) and the ICER for infliximab compared with adalimumab was 209,572 pounds sterling per QALY gained.

Sensitivity analyses indicated that the ICER for adalimumab compared with DMARD was particularly sensitive to alternative model inputs for HAQ progression and utility values; using the Toronto data set for HAQ progression resulted in an ICER of 47,404 pounds sterling per QALY gained, and utility mapping from SF-6D resulted in an ICER of 62,360 pounds sterling per QALY gained.

The Evidence Review Group (ERG) highlighted three important limitations of the clinical evidence.

- There was limited evidence available on the use of adalimumab in the treatment of people with PsA. Only the ADEPT study had so far been fully published.
- Only a proportion of participants in the key adalimumab studies had PsA that
  had failed to respond to at least two DMARDs. The ADEPT study required that
  there had been an inadequate response to nonsteroidal antiinflammatory
  drugs (NSAIDS) rather than DMARDS; therefore, the overall randomised
  controlled trial (RCT) populations treated with adalimumab differed from
  those for which the British Society for Rheumatology (BSR) guidelines
  recommend anti-TNF-alpha therapy. However, independent experts working
  with the ERG advised that the participants in these RCTs represented a
  population with relatively severe PsA, similar to that currently being treated in
  UK clinical practice.
- The ERG noted that the RCTs lacked people with severe skin involvement. Approximately half of people in the ADEPT study had significant skin involvement at baseline (affected body surface area [BSA] equal to or greater than 3%); and mean PASI scores were 7.4 ± 6.1 standard deviation [SD] and 8.3 ± 7.3 SD for people in the adalimumab and placebo arms, respectively. These PASI scores are lower than the scores usually assigned to moderate to severe psoriasis (PASI score of 10 or greater).

The ERG requested more information and revised analyses from the manufacturer around subgroups of people with PsA with and without skin involvement, evidence from trials reported at 12 as well as 24 weeks, and exclusion of the open-label portion of the M02-570 study from the evidence synthesis.

The Appraisal Committee discussed the evidence submitted by the manufacturer on the cost effectiveness of adalimumab compared with DMARDs, etanercept and infliximab, the ERG's critique of the original submission by the manufacturer, the manufacturer's response to the clarifications requested by the ERG, and the further analyses requested by the Institute. The Committee acknowledged the inclusion of the skin component in the economic modelling, which had not been included in the modelling for the previous appraisal of technologies for the treatment PsA (National Institute for Health and Clinical Excellence [NICE] technology appraisal guidance 104).

The Committee discussed the methods used to derive the utilities in the base-case modelling, and raised concerns that the PASI component has a very strong impact on utility function, although the study that underpinned the regression analysis did not include many people with severe skin involvement. The Committee further noted that using an alternative source for the utility data (SF-6D) from the ADEPT study resulted in a substantially higher ICER for adalimumab (62,360 pounds sterling per QALY gained) compared with DMARD than in the original base-case

analysis (25,991 pounds sterling per QALY gained). In addition, the Committee noted that the ICERs were particularly sensitive to the assumptions around HAQ progression, and noted that the HAQ progression in the control arm of the model was based on people treated with palliative care although the modelled patients received DMARDs in the control arm of the manufacturer's model.

The Committee reflected on current NICE guidance for the use of anti-TNF-alpha agents (etanercept and infliximab) in the treatment of adults with PsA (NICE technology appraisal guidance 104). It agreed that because the acquisition costs for adalimumab and etanercept are identical it is reasonable to allow choice between adalimumab and etanercept based on individual circumstances. Consequently, the Committee concluded that the decision regarding which anti-TNF-alpha agent is most appropriate for the treatment of adults with PsA should be made on a case-by-case basis by a specialist physician experienced in the diagnosis and treatment of PsA following full and informed discussion with the patient. Furthermore, the Committee agreed that criteria for the use of adalimumab should be identical to the criteria listed in current NICE guidance for the use of etanercept in the treatment of adults with PsA (NICE technology appraisal guidance 104).

The Committee considered the sequential use of anti-TNF-alpha agents or use of these agents in combination. It concluded that there was currently no evidence supporting the use of more than one anti-TNF-alpha agent either concurrently or sequentially.

Refer to Sections 3 and 4 of the original guideline document for details of the three revised economic analyses provided by the manufacturer, the ERG comments, and the Appraisal Committee considerations.

#### METHOD OF GUIDELINE VALIDATION

External Peer Review

#### **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

Consultee organizations from the following groups were invited to comment on the draft scope, Assessment Report and the Appraisal Consultation Document (ACD) and were provided with the opportunity to appeal against the Final Appraisal Determination.

- Manufacturer/sponsors
- Professional/specialist and patient/carer groups
- Commentator organisations (without the right of appeal)

In addition, individuals selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups were also invited to comment on the ACD.

### **RECOMMENDATIONS**

#### **MAJOR RECOMMENDATIONS**

Adalimumab, within its licensed indication, is recommended as an option for the treatment of adults with active and progressive psoriatic arthritis only when the following criteria are met.

- The person has peripheral arthritis with three or more tender joints and three or more swollen joints.
- The psoriatic arthritis has not responded to adequate trials of at least two standard disease-modifying anti-rheumatic drugs (DMARDs), administered either individually or in combination.

Adalimumab treatment should be discontinued after 12 weeks in adults whose psoriatic arthritis has not shown an adequate response when assessed using the psoriatic arthritis response criteria (PsARC). For the purposes of this guidance, an adequate response is defined as:

 An improvement in at least two of the four PsARC criteria, one of which has to be joint tenderness or swelling score, with no worsening in any of the four criteria.

It is recommended that the use of adalimumab for the treatment of psoriatic arthritis in adults should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of psoriatic arthritis.

## **CLINICAL ALGORITHM(S)**

None provided

#### **EVIDENCE SUPPORTING THE RECOMMENDATIONS**

#### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

#### **POTENTIAL BENEFITS**

Appropriate use of adalimumab for the treatment of psoriatic arthritis in adults

#### **POTENTIAL HARMS**

Common undesirable effects of adalimumab (those observed in 1% or more of people receiving treatment) include infections of the upper respiratory tract and injection-site reactions. The summary of product characteristics (SPC) advises that people are closely monitored for infections before, during and after treatment with adalimumab and that tuberculosis status is evaluated before initiation of therapy. Treatment with adalimumab may also result in the formation of autoimmune antibodies; however, long-term effects of adalimumab on the development of autoimmune diseases are unknown.

## **QUALIFYING STATEMENTS**

#### **QUALIFYING STATEMENTS**

- This guidance represents the view of the Institute, which was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. The guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.
- Because three out of the four studies included in the manufacturer's submission are not fully published and report only preliminary results in abstract form there are insufficient data presented to fully assess their validity. While the data presented in these abstracts is supplemented with additional data provided by the manufacturer in the submission, this supplemental data are not in the public domain and therefore cannot be externally validated. Until these studies are fully published and the complete data made available for evaluation, these results and any assumptions based thereon should be interpreted with due caution.
- Summary of uncertainties and issues:

As a general concern, the Evidence Review Group (ERG) noted a lack of transparency relating to the description of the methods in the manufacturer's submission report. The major concerns raised by the ERG include:

- The approach of the methods of evidence synthesis was overly complex, employing a number of assumptions which increase the possibility of significant bias in the subsequent results.
- The exclusion of relevant 12-week trial evidence from the analysis.
- The use of unnecessary assumptions in order to adjust 24-week trial results to estimate the response rates at 12-weeks (i.e. assuming that the relationship between response rates at 12 and 24-weeks observed for adalimumab applies to all other treatments, and forcing the 12week response rate to be lower than 24-week response rates).
- The robustness of the cost-effectiveness results to different relevant subgroups (e.g. previous use of disease-modifying anti-rheumatic drugs (DMARDs), patients with and without skin involvement).

#### **IMPLEMENTATION OF THE GUIDELINE**

#### **DESCRIPTION OF IMPLEMENTATION STRATEGY**

 The Healthcare Commission assesses the performance of National Health Service (NHS) organisations in meeting core and developmental standards set by the Department of Health in 'Standards for Better Health' issued in July 2004. The Secretary of State has directed that the NHS provides funding and resources for medicines and treatments that have been recommended by National Institute for Health and Clinical Excellence (NICE) technology

- appraisals normally within 3 months from the date that NICE publishes the guidance. Core standard C5 states that healthcare organisations should ensure they conform to NICE technology appraisals.
- 'Healthcare Standards for Wales' was issued by the Welsh Assembly Government in May 2005 and provides a framework both for self-assessment by healthcare organisations and for external review and investigation by Healthcare Inspectorate Wales. Standard 12a requires healthcare organisations to ensure that patients and service users are provided with effective treatment and care that conforms to NICE technology appraisal guidance. The Assembly Minister for Health and Social Services issued a Direction in October 2003 which requires Local Health Boards and NHS Trusts to make funding available to enable the implementation of NICE technology appraisal guidance, normally within 3 months.
- NICE has developed tools to help organisations implement this guidance (listed below). These are available on NICE website (<a href="www.nice.org.uk">www.nice.org.uk</a>).
  - A costing statement explaining the resource impact of this guidance
  - Audit criteria to monitor local practice

#### **IMPLEMENTATION TOOLS**

Audit Criteria/Indicators
Patient Resources
Quick Reference Guides/Physician Guides
Resources

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

# INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

#### **IOM CARE NEED**

Getting Better Living with Illness

### **IOM DOMAIN**

Effectiveness Patient-centeredness

#### **IDENTIFYING INFORMATION AND AVAILABILITY**

#### **BIBLIOGRAPHIC SOURCE(S)**

National Institute for Health and Clinical Excellence (NICE). Adalimumab for the treatment of psoriatic arthritis. London (UK): National Institute for Health and Clinical Excellence (NICE); 2007 Aug. 26 p. (Technology appraisal guidance; no. 125).

#### **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

#### **DATE RELEASED**

2007 Aug

### **GUIDELINE DEVELOPER(S)**

National Institute for Health and Clinical Excellence (NICE) - National Government Agency [Non-U.S.]

#### **SOURCE(S) OF FUNDING**

National Institute for Health and Clinical Excellence (NICE)

#### **GUIDELINE COMMITTEE**

Appraisal Committee

#### **COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE**

Committee Members: Professor David Barnett Professor of Clinical Pharmacology, University of Leicester; Dr David W Black Director of Public Health, Derbyshire County PCT; Mr Brian Buckley Chairman, Incontact; Dr Carol Campbell Senior Lecturer, University of Teesside; Professor Mike Campbell Professor of Medical Statistics, University of Sheffield; Professor David Chadwick Professor of Neurology, Liverpool University; Mr Richard Devereaux-Phillips Public Affairs Manager, Medtronic; Professor Rachel A Elliott Lord Trent Professor of Medicines and Health, Nottingham University; Mrs Eleanor Grey Lay member; Dr Peter Jackson Clinical Pharmacologist, University of Sheffield; Professor Peter Jones Pro Vice Chancellor for Research & Enterprise, Professor of Statistics, Keele University; Ms Rachel Lewis Practice Development Facilitator, Manchester PCT; Damien Longson Consultant in Liaison Psychiatry, North Manchester General Hospital; Professor Jonathan Michaels Professor of Vascular Surgery, University of Sheffield; Dr Eugene Milne Deputy Medical Director, North East Strategic Health Authority; Dr Simon Mitchell Consultant Neonatal Paediatrician, St Mary's Hospital, Manchester; Dr Katherine Payne Health Economics Research Fellow, University of Manchester; Dr Martin J Price Head of Outcomes Research, Janssen-Cilag; Professor Andrew Stevens Chair of Appraisal Committee C; Dr Cathryn Thomas Senior Lecturer, University of Birmingham

#### FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

#### **GUIDELINE STATUS**

This is the current release of the guideline.

#### **GUIDELINE AVAILABILITY**

Electronic copies: Available in Portable Document Format (PDF) format from the National Institute for Health and Clinical Excellence (NICE) Web site.

#### **AVAILABILITY OF COMPANION DOCUMENTS**

The following are available:

- Adalimumab for the treatment of psoriatic arthritis. Quick reference guide. London (UK): National Institute for Health and Clinical Excellence (NICE); 2007 Aug. 1 p. (Technology appraisal 125). Available in Portable Document Format (PDF) from the <u>National Institute for Health and Clinical Excellence</u> (NICE) Web site.
- Adalimumab for the treatment of psoriatic arthritis. Costing statement. London (UK): National Institute for Health and Clinical Excellence (NICE); 2007 Aug. 15. 1 p. (Technology appraisal 125). Available in Portable Document Format (PDF) from the NICE Web site.
- Adalimumab for the treatment of psoriatic arthritis. Audit criteria. London (UK): National Institute for Health and Clinical Excellence (NICE); 2007 Aug. 21. 10 p. (Technology appraisal 125). Available in Portable Document Format (PDF) from the <u>NICE Web site</u>.
- Adalimumab for the treatment of psoriatic arthritis. Evidence Review Group report. London (UK): National Institute for Health and Clinical Excellence (NICE); 2007 Aug. 21. 160 p. (Technology appraisal 125). Available in Portable Document Format (PDF) from the <u>NICE Web site</u>.
- Guide to the single technology appraisal process. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 Sept 19. 44 p. Available in Portable Document Format (PDF) from the <u>NICE Web site</u>.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. ref: 125. 11 Strand, London, WC2N 5HR.

#### **PATIENT RESOURCES**

The following is available:

Adalimumab for the treatment of psoriatic arthritis. Understanding NICE guidance - Information for people who use NHS services. London (UK):
 National Institute for Health and Clinical Excellence (NICE); 2007 Aug. 14. 4
 p. (Technology appraisal 125).

Available in Portable Document Format (PDF) from the NICE Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

#### **NGC STATUS**

This NGC summary was completed by ECRI Institute on October 17, 2007.

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